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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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20

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

09/065,902

Applicant(s)

TANZI ET AL.

Examiner

Karen Clemens

Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 March 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 26 March 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (see NOTE below);
- (b) ☐ they raise the issue of new matter. (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

4. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
6. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
- Claim(s) allowed: 9 and 10.
- Claim(s) objected to: _____.
- Claim(s) rejected: 2-5.
- Claim(s) withdrawn from consideration: 6-8 and 12.
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
11. ☐ Other:

Continuation of 4.

Applicant's reply has overcome the following rejection(s): Applicant's submission of the Declaration Under 37 C.F.R. 1.132, filed 3/26/01, which invalidates Tanzi et al. as a prior art reference, is sufficient to overcome the rejection of Claims 9-10 under 35 U.S.C. 103(a) as being unpatentable over Tanzi et al. (Neurobiology of Disease 3:159-168, 1996) in view of Miller et al. (Ann. New York Acad. Sci. 696:133-48, 1993).

However, Claims 2-3 stand rejected under 35 U.S.C. 102(a) as being anticipated by Vito et al. (J. Biol. Chem. 271(49):31025-31028, 1996) for the same reasons set forth in Paper No. 10.

Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Vito et al. (J. Biol. Chem. 271(49):31025-31028, 1996) in view of Dalbow et al. (US Patent #4116776, 1978) for the same reasons set forth in Paper No. 10.

Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Vito et al. (J. Biol. Chem. 271(49):31025-31028, 1996) in view of Janeway et al. (Immunobiology, New York, Current Biology, 1997) for the same reasons set forth in Paper No. 10.

Applicant's argue that the antibody recited in Claim 2 which is "an antibody having binding affinity that is specific only to the purified 20 kDa presenilin 2 C-terminal fragment (PS2-CTF)", is referring to an antibody which binds only the 20 kDa proteolytically cleaved PS2 product and not to the PS2 precursor molecule from which it was derived. Applicant's argue that the antibody taught by Vito et al. teaches an antibody which recognizes both the full length and the C-terminal fragment of PS2. Applicant's further submit that the antibody actually used to detect the 20 kDa PS2 cleavage product in the instant application also recognizes the precursor PS2 polypeptide as well as the proteolytically cleaved C-terminal PS2 fragment, but further note that this is not the antibody that Applicant's have claimed. Applicant's submit that the claimed antibody would not bind full-length PS2 and refer to page 19, lines 16-24 in the specification which discloses:

"In another embodiment, the present invention relates to an antibody having binding affinity specifically to a presenilin 2 proteolytic fragment as described above or specifically to a binding fragment of a presenilin 2 proteolytic fragment. Preferably, an antibody binds specifically to a presenilin 2 proteolytic fragment or binding fragment thereof if it does not bind to presenilin 2."

Applicant's further note that the claimed antibody recognizes only the 20 kDa fragment of PS2 and provide an example of a cleavage site specific antibody and methods of making such antibodies citing the Fosang et al. reference in Exhibit A.

However, the Examiner finds no support in the specification or claims for an antibody that binds to the 20 kDa PS2 proteolytically cleaved fragment and not to the precursor PS2 protein. Further, there is no support in the specification for the generation of an antibody which recognizes the cleavage site in the C-terminal portion of PS2 responsible for the generation of the 20 kDa PS2 C-terminal fragment.

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